TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Form FDA 2830	No. Of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25	Initial Registration	300	1	300	1	300
607.21,607.22, 607.25, 607.26, 607.31	Re-registration	3,300	1	3,300	0.5	1,650
607.21, 607.25, 607.30, 607.31	Product Listing Update	75	1	75	0.25	19
Total						1,969

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–23002 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2799]

SteriGenics International, Inc.; Filing of Food Additive Petition (Animal Use); Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that SteriGenics International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the approval to irradiate various animal feeds and feed ingredients for microbial control.

DATES: Written comments on the petitioner's environmental assessment by November 2, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John D. McCurdy, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0171.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2243) has been filed by SteriGenics International, Inc., 4020 Clipper Ct., Fremont, CA 94538–6540. The petition proposes to amend the food additive regulations on irradiation in the production, processing, and handling of animal feed and pet food in 21 CFR part 579 to approve irradiation in various animal feeds and feed ingredients for microbial control.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment.

Interested persons may, on or before November 2, 1999, submit to the Dockets Management Branch written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, FDA finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: August 25, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–22999 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2729]

Draft Guidance for Industry on BA and BE Studies for Orally Administered Drug Products—General Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''BA and BE Studies for Orally Administered Drug Products—General Considerations.'' This draft guidance provides recommendations to sponsors and applicants intending to submit bioavailability (BA) and/or bioequivalence (BE) information in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and their amendments and supplements, to the Center for Drug Evaluation and Research (CDER). This draft guidance provides general information on how to comply with the BA and BE requirements for orally administered dosage forms in 21 CFR part 320. It is one of a set of planned core guidances designed to reduce and/or eliminate the need for FDA drug-specific BA/BE guidances.

DATES: Written comments on the draft guidance document may be submitted by November 2, 1999. Interested parties are invited to submit information specifically to support or refute some of the approaches in the draft guidance that are intended to reduce regulatory burden. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for